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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/814,257	03/21/2001	Nancy D. Hanson	180.00030102	6204

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MUETING, RAASCH & GEBHARDT, P.A.
P.O. BOX 581415
MINNEAPOLIS, MN 55458

EXAMINER

LU, FRANK WEI MIN

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 09/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/814,257

Applicant(s)

HANSON ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17,39-49 and 51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-16 is/are allowed.
- 6) ☒ Claim(s) 17,43,45 and 49 is/are rejected.
- 7) ☒ Claim(s) 39-42,44,46-48 and 51 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Response to Amendment

1. IDS filed on August 17, 2001 and applicant's response to the office action filed on November 14, 2001 has been entered as Paper Nos: 5 and 7. The claims pending in this application are claims 12-17, 39-49, and 51. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn.

Specification

2. The substituted specification including pages 48-51 filed on November 14, 2001 has been accepted and entered by the office.

Claim Rejections - 35 U.S.C. § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 17 and 43 and are rejected under 35 U.S.C. 102(a) as being anticipated by Vahaboglu *et al.*, (J. Clin. Microbiology, 36, 827-829, March 1998).

Vahaboglu *et al.*, teach the detection and identification of OXA-10-derived ceftazidime-hydrolyzing extended-spectrum β -lactamases in clinical samples from Turkey. PCR was designed to amplify a 720 bp fragment of OXA-10, -17, -11, -14 and -16 genes with a sense

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primer OPR1 and an antisense primers OPR2 of beta lactamase OXA-10 as recited in claim 43.

Restriction enzyme digestion and DNA sequencing were used to differentiate different OXA subtypes (see pages 827 and 828 and Figure 1).

Therefore, Vahaboglu *et al.*, teach all limitations recited by claims 17 and 43.

5. Claims 17 and 45 are rejected under 35 U.S.C. 102(a) as being anticipated by Speldooren *et al.*, (Antimicrobial Agents and Chemotherapy, 42, 879-884, April 1998).

Speldooren *et al.*, teach discriminatory detection of inhibitor-resistant beta-lactamases in *Escherichia coli* from clinical samples by single-stranded conformation polymorphism-PCR.

Beta-lactamases TEM and OXA-1 primers as recited in claim 45 were used for PCR (see abstract in page 879 and left column in page 880). A OXA-1 specific PCR product was generated using DNA from Strain 4P4 and its sequence was determined (see page 882).

Therefore, Speldooren *et al.*, teach all limitations recited by claims 17 and 45.

6. Claims 17 and 45 are rejected under 35 U.S.C. 102(a) as being anticipated by Siu *et al.*, (APMIS, 106, 917-920, September 1998).

Siu *et al.*, teach to PCR the OXA-1 like enzyme using primers A and B known to be specific for beta lactamase OXA- 1 and -4. OXA-1 -like beta-lactamase was identified by a PI of 7.4 followed by PCR amplification and positive hybridization with an OXA-1 probe (see abstract in page 917 and right column in page 918).

Therefore, Siu *et al.*, teach all limitations recited by claims 17 and 45.

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Response to Arguments

In page 7, fourth paragraph of applicant's remarks, applicant argued that "cited documents fail to teach all of the elements of Applicant's claimed invention." since "the prior art teaches a method of detecting specific members of a beta-lactamase family."

The argument has been fully considered but it is not persuasive toward the withdrawal of the rejection because, although the examiner agreed with applicant that "the prior art teaches a method of detecting specific members of a beta-lactamase family.", cited prior art did teach all limitations recited in claim 17 (see above rejections).

Claim Rejections - 35 U.S.C. § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vahaboglu *et al.*, (1998) as applied to claims 17 and 45 above, and further in view of Fluit *et al.*, (WO91/08305, published on June 13, 1991).

The teachings of Vahaboglu *et al.*, have been summarized previously, *supra*. The bacteria isolates in Table 1 (page 828) could be considered as the positive and negative controls as recited in 49.

Vahaboglu *et al.*, do not disclose a bacteria diagnostic kit as recited in claim 49.

Fluit *et al.*, do teach a bacteria diagnostic kit (see pages 24 and 25).

Therefore, in the absence of an unexpected result, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have organized the components and method taught by Vahaboglu *et al.*, into a kit because the method for identifying a beta-lactamase in a clinical sample using PCR was known at that time the inventions were made and the kit format was utilized not only assemble a variety of different reagents together but ensured the quality and compatibility of the reagents. Fluit *et al.*, would have motivated and suggested the assemblage of reagent (s) of biotechnology methods into a kit in order to obtain the above discussed advantages, thus resulting in instant kit described in claim 49. One having ordinary skill in the art at the time the invention was made would have been a reasonable expectation of success to combine these prior art together because the kit could provide a convenient, efficient, economical way to practice the method of Vahaboglu *et al.*.

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Response to Arguments

In page 10, third paragraph of applicant's remarks, applicant argued that "the cited documents fail to teach a diagnostic kit for detecting all members of the OXA-family beta-lactamase" and failed to teach or suggest the claimed invention as recited in claim 49.

The argument has been fully considered but it is not persuasive toward the withdrawal of the rejection. First, the combination of prior art from Vahaboglu *et al.*, and Fluit *et al.*, did teach the claimed invention as recited in claim 49. Second, claim 49 is not required to detect all members of the OXA-family beta-lactamase as suggested by applicant, which is not recited in the rejected claim 49. However, claim 49 is directed to a diagnostic kit for detecting an OXA family beta-lactamase. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR

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1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Claims 12-16 are allowed over prior art.

11. Claims 39-42, 44, 46-48, and 50 are objected to as being dependent upon a rejected base claim, but appear to be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (703) 305-1270. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.


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Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
September 6, 2002


BRADLEY L. SISSON
PRIMARY EXAMINER
GROUP ~~1800~~ 1630